K081665

JUN 27 2008

510(k) Summary (as required by 21 CFR 807.92(c))

Manufacturer Name and Address
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Date Prepared
March 14, 2008 [Revised on June 26, 2008]

Name of Device
MILLENIUM II

Classification Name
Wheelchair, Mechanical

Identification of Predicate Device
Invacare Tracer K935398

Description of the Device
Intended Use
The Millenium II wheelchairs are intended to provide mobility to persons limited to a seated position that are capable of operating a manual wheelchair.

Comparison to Predicate Device
This device has a similar intended use and technological characteristics as the predicate device. The main differences are the Millenium offers additional seat widths, axle to accommodate a travel wheel (the travel wheel is not part of this submission), and the wheel locks are push to lock only. The device and predicate device are both mechanical wheelchairs.

Non-Clinical Tests Performed

All applicable tests were voluntarily conducted in accordance with ISO 7176, including Parts 1, 5, 15, 16, and 93. Where applicable a 100 kg dummy (plus 12.4 kg) as specified in ISO 7176 – 11 was used.

Testing to parts 3 and 8 will be completed prior to product launch and commercialization.

Summary

In conclusion we believe the subject device is a low risk device that complies with internationally recognized standards and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2008

NEXT Mobility, LLC
% Underwriters Laboratories, Inc.
Mr. Jeff D. Rongero
12 Laboratory Drive
Research Triangle, NC 27709

Re: K081665
Trade/Device Name: Millenium II
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: June 12, 2008
Received: June 13, 2008

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Millenium II

Indications For Use:

The Millenium wheelchairs are intended to provide mobility to persons limited to a seated position that are capable of operating a manual wheelchair.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Page 1 of 1
Division of General, Restorative, and Neurological Devices

510(k) Number K081605